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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,687	08/07/2006	Isabelle Rault	33379-US-PCT	4963

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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,687	RAULT ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The abstract is objected to because the abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Appropriate correction is required. See MPEP § 608.01(b).

2. The title of the invention is not descriptive. The disclosure and claims are limited to coated tablets of diclofenac. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "Coated Diclofenac Tablets".

Claim Rejections - 35 USC § 112 2nd Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 6, it unclear whether the weight calculations for the weight percent are based on the total weight of the tablet core or the total weight

of the tablet with the coating. In claim 7, no units are given for the percentages and it is unclear whether these percentages are solely based on the coating layer of the final tablet or the total composition of the tablet as a whole.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1 – 3 and 5 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomaeus et al. (US 6,558,701).

Bartholomaeus et al. discloses a multilayer table with tramadol and diclofenac and/or their physiologically compatible salts with the active substances being separated from one another by a separating layer (col 1, ln 16 – 20). Among the physiologically compatible salts of diclofenac is diclofenac potassium (col 2, ln 12). The tablet can consist of three, five or seven layers (col 1, ln 65 – 67). Each layer contains conventional auxiliary substances (col 2, ln 16 – 19). In the examples (beginning at col 6, ln 19), the separating layer (coating) comprises microcrystalline cellulose (MCC; 70% of the layer), hydroxypropylmethyl cellulose (HPMC; 27% of the separating layer) and magnesium stearate (1% of the separating layer). The diclofenac containing layer contains MCC, and HPMC. Based on the tabletting compression order described, the diclofenac layer is not in the core of the tablet.

Bartholomaeus et al. does not explicitly disclose a tablet in which an interior layer containing diclofenac is coated with the intermediate layer nor the use of stearic acid.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a tablet with more than 3 layers or with diclofenac in the core, as taught by Bartholomaeus et al., to arrive at a tablet dosage form having a core

of diclofenac and a coating layer. Stearic acid is taught by Bartholomaeus as functionally equivalent the magnesium stearate used in the examples (col 3, ln 51).

The amount of the specific ingredients in the coating composition is a result effective parameter that a person of ordinary skill in the art would routinely optimize to alter the physical properties (e.g., hardness or compressibility of the tablet) and the release characteristics of the tablet. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results.

9. Claims 1 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomaeus et al. as applied to claims 1 – 3 and 5 – 7 above, and further in view of Humbert-Droz et al. (US 6,083,531).

Bartholomaeus et al. discloses a multilayer tablet dosage form of diclofenac and a separating (coating) layer comprised of HPMC, MCC and an excipient such as stearic acid. Each tablet contains 50 mg of diclofenac sodium.

Bartholomaeus et al. does not disclose a diclofenac dosage of 12.5 mg diclofenac potassium.

Humbert-Droz et al. discloses fast melt oral dosage form that contain 12.5 mg of diclofenac potassium per unit (examples 1 – 5).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a multilayer tablet dosage from as taught by Bartholomaeus et al. containing 12.5 mg of diclofenac potassium, taught by Humbert-Droz et al. as an useful dosage of diclofenac when orally administered.

10. Claims 1 – 3 and 5 – 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomaeus et al. as applied to claims 1 – 3 and 5 – 7 above, and further in view of Kurihara et al. (US 4,341,563).

Bartholomaeus et al. discloses a multilayer tablet dosage form of diclofenac and a separating (coating) layer comprised of HPMC, MCC and an excipient such as stearic acid. Each tablet contains 50 mg of diclofenac sodium.

Bartholomaeus et al. does not disclose the inclusion of titanium dioxide in the separating layer.

Kurihara et al. discloses protective coatings which prevent degeneration or decomposition of the active ingredient due to hygroscopic or other causes either in the process of manufacture or during the storage time until it is administered (col 1, ln 26 – 32). Among the water soluble film bases used are HPMC. Food pigments or coloring agents such as titanium dioxide may be added (col 4, ln 56 – 58). In table 2 (col 6) and table 1, composition 1, compositions comprising various amounts of HPMC (70 – 80% HPMC when the weight water used to prepare the coating solution is excluded) and stearic acid (8.35, 16.4, 16.7 or 30% when the weight of the water used to prepare the coating solution is excluded) are shown. The relative amounts of the ingredients can

alter the moisture permeability and the workability of the coating composition during the manufacture procedure (see tables 1 and 2; col 7, ln 14 – 16).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a multilayer tablet dosage from as taught by Bartholomaeus et al. and to add titanium dioxide to the coating layer, as taught by Kurihara et al. Kurihara et al. also provides additional information on the amounts of the various ingredients such as HPMC and stearic acid which may be present in the separating layer.

11. Claims 1, 2 and 5 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ting et al. (WO 99/51209).

Ting et al. discloses press coated oral drug delivery forms (abstract) that can be a tablet (p 3, ln 17). As can be seen in figure 1, the immediate release compartment forms a core which is surrounded by an extended release compartment or coating. In table 1 (p 17), the immediate release compartment contains active ingredient and MCC. The extended release compartment contains additional active ingredient, ~30% HPMC, ~30% MCC and ~20% hydrogenated vegetable oil (based on the additional weight of the extended release compartment only). Ranges for the various ingredients are shown in table 2 (p 18).

Ting et al. does not disclose an example with diclofenac sodium as the active ingredient or with stearic acid.

Ting et al. does disclose that diclofenac sodium is among the active ingredients suitable for use in this dosage form (p 5, ln 19). Ting et al. also discloses that while hydrogenate vegetable oil type 1 is the further preferred hydrophobic polymer, stearic acid may also be used as the hydrophobic polymer present in the drug delivery system (p 8, ln 18 – 22).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a dosage form as taught by Ting et al. to prepare are diclofenac dosage form and to use stearic acid in the formulation, taught by Ting et al. as functionally equivalent to the hydrogenate vegetable oil used in the exemplified dosage forms of Ting et al.

The amount of the specific ingredients in a various parts of the composition is a result effective parameter that a person of ordinary skill in the art would routinely optimize to alter the physical properties (e.g., hardness or compressibility of the tablet) and the release characteristics of the tablet. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results.

12. Claims1 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ting et al. as applied to claims 1, 2 and 5 – 7 above, and further in view of Humbert-Droz et al. (US 6.083,531).

Ting et al. discloses a tablet dosage form with an immediate release core surrounded by and extended release coating layer. The immediate release core can contain MCC in addition to the active ingredient while the coating can contain HPMC, MCC and a hydrophobic polymer such as hydrogenate vegetable oil or stearic acid.

Ting et al. does not disclose dosage information for diclofenac or the use of diclofenac potassium.

Humbert-Droz et al. discloses that diclofenac in either the free base or in the potassium or sodium salt forms can be used in the dosage form (col 2, ln 38 – 40). The fast melt oral dosage forms prepared contained 12.5 mg of diclofenac potassium per unit (examples 1 – 5).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a diclofenac containing dosage form as taught by Ting et al. and to use diclofenac potassium as the physiologically acceptable salt form of the active ingredient as taught by Bartholomaeus et al. and to formulate the unit dosage to contain 12.5 mg of diclofenac potassium, as taught by Humbert-Droz et al.

13. Claims 1 – 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ting et al. as applied to claims 1, 2 and 5 – 7 above, and further in view of Humbert-Droz et al. as applied to claims 1 – 7 above, and further in view of Kurihara et al. (US 4,341,563).

Ting et al. discloses a tablet dosage form with an immediate release core surrounded by and extended release coating layer. The immediate release core can

contain MCC in addition to the active ingredient while the coating can contain HPMC, MCC and a hydrophobic polymer such as hydrogenate vegetable oil or stearic acid. Humbert-Dolz et al. teaches that diclofenac sodium or diclofenac sodium may be used and that a suitable unit dose of diclofenac potassium is 12.5 mg.

None of the references disclose the use of titanium dioxide.

Kurihara et al. discloses protective coatings which prevent degeneration or decomposition of the active ingredient due to hygroscopic or other causes either in the process of manufacture or during the storage time until it is administered (col 1, ln 26 – 32). Among the water soluble film bases used are HPMC. Food pigments or coloring agents such as titanium dioxide may be added (col 4, ln 56 – 58). In table 2 (col 6) and table 1, composition 1, compositions comprising various amounts of HPMC (70 – 80% HPMC when the weight water used to prepare the coating solution is excluded) and steraic acid (8.35, 16.4, 16.7 or 30% when the weight water used to prepare the coating solution is excluded) are shown. The relative amounts of the ingredients can alter the moisture permeability and the workability of the coating composition during the manufacture procedure (see tables 1 and 2; col 7, ln 14 – 16).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a immediate and extended release tablet dosage from as taught by Ting et al. and to add titanium dioxide to the external layer to produce a white outer coating, as taught by Kurihara et al. Kurihara et al. also provides additional information on the amounts of the various ingredients such as stearic acid and HPMC which may be present in the separating layer.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW